



INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)									ATTY. DOCKET NO. PC25240A		SERIAL NO. 10/763,340			
									APPLICANT Timothy A. Hagen, et al.					
									FILING DATE January 23, 2004		GROUP 1615			
U.S. PATENT DOCUMENTS														
EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
PJA	US	5	1	6	9	6	4	5	12/8/92	Shukla, et al.	424	499		
	US	5	6	3	3	0	0	6	5/27/87	Catania, et al.	424	441		
	US	5	6	0	5	8	8	9	2/25/87	Curatolo, et al.	514	29		
	US	5	7	0	5	1	9	0	1/6/98	Broad, et al.	424	465		
	US	5	7	4	7	0	5	8	5/5/88	Tipton, et al.	424	423		
	US	6	0	6	8	8	5	9	5/30/00	Curatolo, et al.	424	490		
	US	6	2	4	8	3	6	3	8/19/01	Patel, et al.	424	497		
	US	6	5	0	0	4	5	9	12/31/02	Chhabra, et al.	424	474		
	US	6	5	6	9	4	6	3	5/27/03	Patel, et al.	424	497		
	US	6	5	7	6	2	5	8	6/10/03	Koller, et al.	424	458		
PJA	US	6	6	8	2	7	5	9	1/27/04	Lim, et al.	424	468		
	US	6	6	8	2	7	6	7	2/17/04	Burnside, et al.	424	489		
FOREIGN PATENT DOCUMENTS														
DOCUMENT NUMBER									DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
									m/d/y				YES	NO
PJA	WO	9	5	0	9	6	0	1	4/13/95	International	A61K	7/16		
	WO	9	8	1	8	6	1	0	5/7/98	International	B29C	47/04		
	WO	9	8	5	8	3	5	7	12/17/98	International	A61K	9/20		
	WO	0	3	1	8	0	3	1	3/6/03	International	A61K	31/7052		
	WO	0	3	3	7	3	0	4	5/8/03	International	A61K	9/16		
	WO	0	3	5	3	4	0	2	7/3/03	International	A61K	9/00		
	WO	0	3	6	3	8	3	4	8/7/03	International	A61K	9/16		
PJA	WO	0	4	0	0	8	6	5	12/31/03	International	A61K	31/7048		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)														
Curatolo, et al., US Patent Application Publication No. US 2002/0009433, Application No. 09/788,888, Published 1/24/02														
Dunne, U.S. Patent Application Publication No. US 2004/0023898, Application No. 10/628,102, Published 2/5/04														

EXPRESS MAIL NO. EV271824289 US.



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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
<i>PA</i>		Foulds, G., et al., "The effects of an antacid or cimetidine on the serum concentrations of azithromycin", J. Clin. Pharmacol. 1991 Feb; 31(2): 164-7 (Abstract)	
<i>TRP</i>		Amsden, G.W., et al., "Serum and WBC pharmacokinetics of 1500 mg of azithromycin when given either as a single dose or over a 3 day period in healthy volunteers", J. Antimicrobial Chemotherapy (2001), 47(1), 61-68 (Abstract)	
		Zithromax[®] azithromycin tablet 250 mg, Quantitative Composition of the Tablet Blend,	
		Zithromax[®] azithromycin for oral suspension composition 200 mg/5mL, 200mg/5mL Drug Product,	
		Zithromax[®] azithromycin for oral suspension composition 1 gram sachet, Quantitative Composition of the Drug Product,	
		Zithromax[®] azithromycin for oral suspension composition 100 mg/5mL, Quantitative Compositions of the Drug Products	
		Zithromax[®] (azithromycin tablets and azithromycin for oral suspension), Full U.S. Prescribing Information, 70-6170-00-4	
		Zithromax[®] (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Prescribing Information, 69-4763-00-9	
<i>[scribble]</i>		*Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Products with Therapeutic Evaluations, 24th Edition, Orange Book Listings of Azithromycin Dosage Forms	
EXAMINER <i>[Signature]</i>		DATE CONSIDERED <i>5-16-2005</i>	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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**SUPPLEMENTAL INFORMATION
DISCLOSURE CITATION**

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U.S. PATENT DOCUMENTS

EXAMINE R INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
HA	US 2 9 5 5 9 5 6	10/11/1960	Baugh, et al.	117	100	
	US 4 0 5 3 2 6 4	10/11/1977	King	425	8	
	US 4 0 8 6 3 4 6	4/25/1978	Bocker, et al.	424	253	
	US 4 0 9 2 0 8 9	5/30/1978	Bocker, et al.	425	10	
	US 4 2 9 3 5 7 0	10/06/1981	Vadasz	426	3	
	US 4 4 7 4 7 6 8	10/02/1984	Bright	424	180	
	US 4 5 1 7 3 5 9	05/14/1985	Kobrehel, et al.	538	7.4	
	US 4 6 7 5 1 4 0	06/23/1987	Sparks, et al.	264	4.3	
	US 4 8 7 4 6 1 1	10/17/1989	Wilson, et al.	424	410	
	US 4 9 3 1 2 8 5	08/05/1990	Edgren, et al.	424	473	
	US 4 9 5 7 6 8 1	09/18/1990	Klimesch, et al.	264	211.23	
	US 4 9 6 3 5 3 1	10/16/1990	Remington, et al.	514	29	
	US 5 0 1 9 3 0 2	05/28/1991	Sparks, et al.	264	8	
	US 5 0 2 4 8 4 2	06/18/1991	Edgren, et al.	424	473	
	US 5 0 4 7 2 4 4	09/10/1991	Sanvordeker, et al.	424	435	
	US 5 0 6 4 6 5 0	10/12/1991	Lew	424	435	
	US 5 0 8 4 2 8 7	01/28/1992	Ghebre-Sellassie, et al.	424	495	
	US 5 1 0 0 5 9 2	03/31/1992	Sparks, et al.	264	7	
	US 5 1 6 0 7 4 3	11/03/1992	Edgren, et al.	424	473	
	US 5 1 4 3 6 6 2	09/1/1992	Chesterfield, et al.	264	8	
	US 5 1 8 3 6 9 0	02/02/1993	Carr, et al.	427	213.31	
	US 5 1 9 4 2 6 2	03/16/1993	Goldberg, et al.	424	401	
	US 5 1 9 6 1 9 9	03/23/1993	Fulsz	424	401	
	US 5 2 1 3 8 1 0	05/25/1993	Steber	424	490	
	US 5 2 3 6 7 3 4	08/17/1993	Fulsz	426	641	
	US 5 2 9 2 6 5 7	03/08/1994	Rutherford, et al.	435	243	
HA	US 5 3 4 8 7 5 8	09/20/1994	Fulsz, et al.	426	660	

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Page 2 of 7										ATTY. DOCKET NO. PC25240A			SERIAL NO. 10/763,340		
										APPLICANT Timothy A. Hagen, et al.					
										FILING DATE January 23, 2004			GROUP 1615		
PA	US	5	3	8	0	4	7	3	01/10/1995	Boque, et al.	264	11			
	US	5	4	0	5	6	1	7	04/11/1995	Gowan, Jr., et al.	424	464			
	US	5	4	0	7	6	7	6	04/18/1995	Fulsz	424	401			
	US	5	4	2	9	8	3	6	07/04/1995	Fulsz	426	601			
	US	5	4	3	3	9	5	1	07/18/1995	Serajuddin, et al	424	486			
	US	5	4	5	6	9	3	2	10/10/1995	Fulsz, et al	426	548			
	US	5	5	4	9	9	1	7	08/27/1996	Cherukuri, et al.	426	96			
	US	5	4	6	1	0	8	9	10/24/1995	Handyside, et al.	523	171			
	US	5	5	0	0	1	6	2	03/19/1996	Theisen, et al	264	9			
	US	5	5	0	1	8	5	8	03/26/1996	Fulsz	424	439			
	US	5	5	0	5	9	8	3	04/09/1996	Kamada	427	2.21			
	US	5	5	1	8	7	3	0	05/21/1996	Fulsz	424	426			
	US	5	5	3	9	0	0	0	07/23/1996	Leonard	514	682			
	US	5	5	4	9	9	1	7	08/27/1996	Cherukuri, et al.	426	96			
	US	5	5	5	6	6	5	2	09/17/1996	Cherukuri, et al	426	5			
	US	5	5	6	9	4	6	7	10/29/1996	Ruiz	424	489			
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	US	5	5	9	7	8	4	4	01/28/1997	Chauhan, et al.	514	400			
	US	5	6	0	1	7	6	1	02/11/1997	Hoffman, et al.	264	4.3			
	US	5	6	8	3	7	2	0	11/04/1997	Myers, et al.	424	489			
	US	5	6	9	0	9	5	9	11/25/1997	Palepu, et al.	424	472			
	US	5	7	0	7	6	4	6	01/13/1998	Yajima, et al.	424	439			
	US	5	7	3	3	5	7	7	03/31/1998	Myers, et al.	424	488			
	US	5	7	4	1	5	1	9	04/21/1998	Rosenberg, et al.	424	464			
	US	5	7	4	4	1	8	0	08/28/1998	Cherukuri, et al	426	99			
	US	5	7	6	6	5	2	1	08/16/1998	Le Thiesse et al.	264	7			
PA	US	5	7	9	2	4	7	4	08/11/1998	Rauchfuss	424	489			

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									FILING DATE January 23, 2004			GROUP 1615		
PH	US	5	8	2	4	3	4	2	10/20/1998	Chenukuri, et al.	424	484		
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	US	5	8	5	1	5	5	3	12/22/1998	Myers, et al.	424	488		
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	US	5	8	5	5	9	1	5	01/05/1999	Pinkus	242	486		
	US	5	8	6	9	0	9	8	02/09/1999	Misra, et al.	424	484		
	US	5	8	6	9	1	0	1	02/09/1999	Moller, et al	424	489		
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	US	5	8	9	1	8	4	5	04/06/1999	Myers	514	11		
	US	5	9	1	2	0	3	0	06/15/1999	Huzinec, et al.	426	3		
	US	5	9	1	9	4	8	9	07/06/1999	Saleki-Gerhardt, et al.	424	501		
	US	5	9	3	5	6	0	0	08/10/1999	Chenukuri, et al.	424	464		
	US	5	9	4	8	4	0	7	09/07/1999	McGuinness, et al.	424	184.1		
	US	5	9	5	2	0	0	4	09/14/1999	Rudnic, et al.	424	455		
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	US	5	9	6	5	1	6	1	10/12/1999	Oshlack, et al.	424	457		
	US	5	9	6	5	1	6	4	10/12/1999	Fulsz, et al.	424	489		
	US	5	9	7	2	3	7	3	10/26/1999	Yajima, et al.	424	439		
	US	5	9	8	0	9	4	1	11/09/1999	Raiden, et al.	424	464		
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	US	6	0	5	1	2	5	3	04/18/2000	Zettler, et al.	424	465		
	US	6	0	7	7	5	4	1	06/20/2000	Chen, et al.	424	480		
	US	6	0	8	3	4	3	0	07/04/2000	Fulsz, et al.	284	5		
	US	6	0	8	6	9	2	0	07/11/2000	Frisbee, et al.	424	489		
PH	US	6	0	9	0	8	3	0	07/18/2000	Myers, et al.	514	356		

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PT	US	6	1	0	3	2	6	4	08/15/2000	Hoffmann, et al.	424	468	
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	US	6	1	6	5	5	1	2	12/26/2000	Mezaache, et al.	424	489	
	US	6	2	2	1	3	6	8	04/21/2001	Breitenbach, et al.	424	400	
	US	6	2	6	1	5	9	9	07/17/2001	Oshlack, et al.	424	457	
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	US	6	3	2	8	9	9	3	12/11/2001	Linder, et al	424	451	
	US	6	3	3	5	0	3	3	01/01/2002	Oshlack, et al.	424	457	
	US	6	3	8	3	5	1	0	05/07/2002	Linder, et al.	424	436	
	US	6	3	9	5	3	0	0	05/28/2002	Straub, et al.	424	489	
	US	6	5	5	1	6	1	6	04/22/2003	Notario, et al.	424	464	
	2001	0	0	0	3	5	9	0	6/01	Joshim et al	424	465	
	2001	0	0	0	6	6	5	0	7/01	Burnside	424	486	
	2002	0	0	0	9	4	3	3	1/02	Curato	424	34.1	
	2002	0	0	0	9	4	3	3	01/24/2002	Curatolo, et al	424	34.1	
	2002	0	0	2	5	3	4	2	02/28/2002	Linder, et al	424	489	
	2002	0	0	4	4	9	6	8	04/18/2002	Van Lengerich	424	469	
	2005	0	0	2	6	8	5	1	02/03/2005	Danilovski, et al.	514	28	
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	2003	0	2	2	8	3	5	7	12/11/2003	Johnson, et al.	424	465	
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	2004	0	0	1	4	9	5	1	01/22/2004	Dumic et al	536	7.1	
	US	6	3	6	5	5	7	4	04/02/2002	Singer et al.	514	29	
	US	6	2	4	5	9	0	3	06/12/2001	Karimian, et al.	536	7.4	
RV	2004	0	1	2	1	0	0	3	06/24/2004	Chickering, III et al.	424	465	

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PH	US	6	6	8	9	3	9	0	02/10/2004	Bernstein, et al.	424	501	
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PH	US	6	6	4	5	5	2	8	11/11/2003	Straub, Ket al.	424	489	

FOREIGN PATENT DOCUMENTS														
DOCUMENT NUMBER									DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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PH	IN	1	8	7	4	8	7		24 May 00	Indian	A61K	9/10		
	WO	9	1	0	7	1	7	1	30 May 91	International	A61K	9/16		
	WO	9	4	0	0	1	1	2	06 Jan 94	International	A61K	9/22		
	WO	9	4	2	7	5	5	7	8 Dec 94	International	A61			
	WO	9	8	0	6	7	1	4	19 Feb 98	International	C07D	311/74		
	WO	9	8	4	6	2	3	9	22 Oct 98	International	A61K	31/71		
	WO	9	9	0	3	4	5	3	28 Jan 99	International	A61K	9/50		
	WO	9	9	2	4	0	3	1	20 May 99	International	A61K	31/40		
	WO	0	0	2	6	2	8	5	11 May 00	International	C08K	5/103		
	WO	0	0	5	7	8	8	6	05 Oct 00	International	A61K	31/70		
	WO	0	1	4	2	2	2	1	14 Jun 01	International	C07D	231/12		
	WO	0	1	7	8	6	8	8	25 Oct 01	International	A61K	9/24		
	WO	0	1	8	5	1	3	5	15 Nov 01	International	A61K	9/00		
	WO	0	2	2	4	1	7	4	28 Mar 02	International	A61K	6/50		
	WO	4	0	3	5	0	6	3	29 Apr 04	International	A61K	31/7048		
	WO	3	0	3	2	9	2	2	24 Apr 03	International	A61K			
	WO	4	0	0	9	6	0	8	29 Jan 04	International	C07H	17/00		
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PH	EP	0	1	0	9	2	5	3	23 May 84	EPO	C07H	17/00		

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PA	EP	0	5	8	2	3	9	6	09 Feb 94	EPO	A61K	31/71		
	EP	0	7	7	6	6	5	8	16 Feb 00	EPO	A61K	7/50		X
	EP	0	9	4	3	3	4	1	22 Sep 99	EPO	A61K	47/48		
	EP	1	1	2	7	5	8	0	29 Aug 01	EPO	A61K	47/10		
	EP	0	9	2	5	7	8	9	30 Jun 99	EPO	A61K	31/7052		
	EP	1	1	2	7	5	8	0	29 Aug 01	EPO	A61K	47/10		
	GB	2	0	6	6	0	7	0	08 Jul 81	United Kingdom	A61K	9/36		
PA	GB	2	0	9	1	0	9	7	28 Jul 82	United Kingdom	A61K	9/36		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)														
PA			Barber, J., "Assignments of the ¹³ C and ¹ H NMR Spectra of Azithromycin in CDCl ₃ ," <i>Magnetic Resonance in Chemistry</i> 29:7(1991)740-743.											
			Barthelemy, P., et al., "Compritol® 888 ATO: An Innovative Hot-Melt Coating Agent for Prolonged-Release Drug Formulations," <i>Europ. J. Pharmaceut. and Biopharmaceutics</i> , 47(1999)87-90.											
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Patent Application
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Timothy A. Hagen, et al. :

APPLICATION NO.: 10/763,340 : Examiner: Pili Asabi Hawes

FILING DATE: January 23, 2004 : Group Art Unit: 1615

TITLE: AZITHROMYCIN DOSAGE FORMS WITH :
REDUCED SIDE EFFECTS

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Commissioner for Patents
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Alexandria, VA 22313-1450

Sir:

RESPONSE TO FINAL OFFICE ACTION

In full response to the final Office Action mailed July 22, 2005, Applicants respectfully present the following remarks.

A response to the July 22, 2005 Office Action is due prior to October 22, 2005. Therefore, the present Response is being timely filed.

OK to Enter
PA 8/19/2005